6/1/5/2000

jc511 U.S. PTO 09/478668 01/06/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Gary A. Bannon, A. Wesley Burks, Jr., Hugh A. Sampson, and Howard Sosin		
Serial No.:	Divisional of 09/141,220	Art Unit:	
Filed:	January 6, 2000	Examiner:	
For:	*METHODS AND REAGENTS FOR DECREASING CLINICAL REACTION TO ALLERGY*		

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including six (6) pages of Form PTO-1449. Most of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/141,220, filed August 27, 1998, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however. Copies of the newly cited documents, which are identified with an asterisk (*), are enclosed.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507.

U.S. Patents

Number	Issue Date	Patentee	Class/Subclass
5,496,554	03-05-1996	Oka, et al.	424/276.1
5,314,991	05-24-1994	Oka, et al.	530/350

Publications

AAS, et al., "Physico-chemical properties and specific activity of a purified allergen (codfish)," *Dev. Biol. Stand.* 29: 90-98 (1975).

BALL, et al., "A major continuous allergenic epitope of bovine beta-lactoglobulin recognized by human IgE binding," *Clin. Exp. Allergy* 24: 758-764 (1994).

BEVIER, "Flea Allergy Dermatitis Testing Breakthrough," *Canine Practice* 22(2-3): 49-50 (1997).

BOCK, "Natural history of severe reactions to foods in young children," *J. Pediatr.* 107: 676-680 (1985).

BOULET, et al. "Inhibitory effects of an anti-IgE antibody E25 on allergen-induced early asthmatic response," *Am J Respir Crit Care Med* 155:1835-1840 (1997).

BSAC Working Party, "Position paper on allergen immunotherapy," *Clin Exp Allergy* 23:1-44 (1993).

BURKS, et al. "Mapping and mutational analysis of the IgE-binding epitopes on Ara h 1, a legume vicilin protein and a major allergen in peanut hypersensitivity," *Eur. J. Biochem.* 245: 334-339 (1997).

BURKS, et al., "Epitope specificity of the major peanut allergen, Ara h II," *J Allergy Clin Immunol.* 95(2):607-11. (1995).

BURKS, et al., "Isolation, identification, and characterization of clones encoding antigens responsible for peanut hypersensitivity," *Int Arch Allergy Immunol.* 107(1-3): 248-50 (1995).

BURKS, et al. "Recombinant peanut allergen Ara h I expression and IgE binding in patients with peanut hypersensitivity," *J. Clinical Invest.* 96: 1715-1721 (1995).

BURKS, et al., "Allergens, IgE, mediators, inflammatory mechanisms. Epitope specificity and immunoaffinity purification of the major peanut allergen, Ara h I," *J Allergy Clin Immunol.* 93(4): 743-50 (1994).

BURKS, et al., "Identification of peanut agglutinin and soybean trypsin inhibitor as minor legume allergens," *Int Arch Allergy Immunol.* 105(2):143-9 (1994).

BURKS, "Allergenicity of peanut and soybean extracts altered by chemical or thermal denaturation in patients with atopic dermatitis and positive food challenges," *J Allergy Clin Immunol* 90(6 pt 1): 889-97 (1992).

BURKS, et al., "Identification and characterization of a second major peanut allergen, Ara h II, with use of the sera of patients with atopic dermatitis and positive peanut challenge," *J Allergy Clin Immunol.* 90(6 Pt 1): 962-9 (1992).

BURKS, et al., "Identification of a major peanut allergen Ara h I, in patients with atopic dermatitis and positive peanut challenge," *J. Allergy Clin. Immunol.* 88:172-179 (1991).

BURKS, et al. "Atopic dermatitis: clinical relevance of food hypersensitivity reactions," *J. Pediatr.* 113: 447-451 (1988).

COLMAN, "Production of proteins in the milk of transgenic livestock: problems, solutions, and successes," *Am. J. Clin. Nutr.* 63(4): 639S-6455S (1996).

COLMAN, "Production of therapeutic proteins in the milk of transgenic livestock," *Biochem. Soc. Symp.* 63: 141-147 (1998).

DAY, "Genetic Modification of Proteins in Food," *Critical Reviews in Food Science and Nutrition* 36(S):S49-S67 (1996).

DEJONG, et al., "Food allergen (peanut)-specific TH2 clones generated from the peripheral blood of a patient with peanut allergy," *J Allergy Clin Immunol.* 98(1): 73-81 (1996).

ELSAYED, et al., "Synthetic allergenic epitopes from the amino-terminal regions of the major allergens of hazel and birch pollen," *Int. Arch. Allergy Appl. Immunol.* 89: 410-415 (1989).

ESPANION, "Methods of production and perspectives for use of transgenic domestic animals," *DTW Dtsch Tierarztl Wochenschr.* 103(8-9):320-8 (1996).

FAHY, et al. "The effect of an anti-IgE monoclonal antibody on the early- and late-phase responses to allergen inhalation in asthmatic subjects," *American J Respir Crit Care Med* 155: 1828-1834 (1997).

FIELDS, et al., "Solid phase peptide synthesis utilizing 9-fluorenylmethoxycarbonyl amino acids," *Int J Pept Protein Res.* 35(3):161-214 (1990).

FOSTER, "Allergy Testing for Skin disease in the Cat *In Vivo* vs *In Vitro* tests," *Veterinary Immunology* 4(3): 111-115 (1993).

GREENE, "Characterization of allergens of the cat flea, Ctenocephalides felis: detection and frrequency of IgE antibodies in canine sera," *Parasit Immunology* 15: 69-74 (1993).

HALLIWELL, "IgE and IgG Antibodies to flea Antigen in Differing Dog Populations," *Veterinary Immunology and immunopathology* 8: 215-223 (1985).

HALLIWELL, "Aspects of the Immunopathogenisis of Flea Allergy Dermatitis in Dogs," *Veterinary Immunology and Immunopathology* 17: 483-494 (1987).

HERIAN, et al. "Identification of soybean allergens by immunoblotting with sera from soy-allergic adults," *Int. Arch. Allergy Appl. Immunol.* 92: 193-198 (1990).

HSU et al. "Inhibition of specific IgE response in vivo by allergen-gene transfer," *Int Immunol* 8:1405-1411 (1996).

KAMINOGAWA, "Food allergy, oral tolerance and immunomodulation--their molecular and cellular mechanisms," *Biosci. Biotech, Biochem.* 60: 1749-1756 (1996).

MCKEON, "IgG and IgE Antibodies Against Antigens of the Cat Flea, Ctenocephalides Felis Felis in Sera of Allergic and Non-allergic Dogs," *Int. J. Parasitology* 24(2):259-263 (1994).

MONERET-VAUTRIN, "Modifications of allergenicity linked to food technologies," *Allerg Immunol* 30(1): 9-13 (1998).

NELSON et al., "Treatment of anaphylactic sensitivity to peanuts by immunotherapy with injections of aqueous peanut extract," *J. Allergy Clin. Immunol.* 99: 744-751 (1997).

NORMAN, et al., "Multicenter study of several doses of ALLER-VAX® Cat peptides in the treatment of cat allergy," *Journal of Allergy and Clinical Immunology* 99: S127 (1997).

OPPENHEIMER et al. "Treatment of peanut allergy with rush immunotherapy,"*J Allergy Clin Immunol.* 90: 256-62 (1992).

PUCHEU-HASTON, "Allergenic cross-reactivities in flea-reactive canine serum samples," *AJVR* 57(7): 1000-1005 (1996).

RAZ, et al., "Intradermal gene immunization: the possible role of DNA uptake in the induction of cellular immunity to viruses," *Proc Nat Acad Sci USA* 91: 9519-9523 (1994).

ROLFSEN, "Detection of specific IgE antibodies towards cat flea (Ctenocephalides felis felis) in patients with suspected cat allergy," *Allergy* 42: 177-181 (1987).

ROONEY , et al., "Antiparallel, intramolecular triplex DNA stimulates homologous recombination in human cells," *Proc. Natl. Acad. Sci. USA* 92: 2141-2144 (1995).

SAMPSON et al., "Fatal and near-fatal anaphylactic reactions to food in children and adolescents," *N Engl J Med* 327: 380-384 (1992).

SAMPSON, "Food allergy and the role of immunotherapy," *J Allergy Clin. Immun.* 90:151-52 (1992).

SAMPSON, et al., "Mechanisms of food allergy," *Annu. Rev. Nutr.* 16: 161-77 (1996).

SCHEMMER, "Efficacy of Alum-Precipitated Flea Antigen for Hyposensitization of Flea-Allergic Dogs," *Seminars in Veterinary Meicine and Surgery (Small Animal)* 2(3): 195-198 (1987).

SHANTI, et al., "Identification of tropomyosin as the major shrimp allergen and characterization of its IgE-binding epitopes," *J. Immunol.* 151, 5354-5363 (1993).

SHIN, et al., "Biochemical and structural analysis of the IgE binding sites on Ara h1, an abundant and highly allergenic peanut protein," *J Biol Chem.* 273(22):13753-9 (1998).

STANLEY, et al., "Peanut hypersensitivity. IgE binding characteristics of a recombinant Ara h I protein," *Adv Exp Med Biol.* 409: 213-6 (1996).

STANLEY, et al., "Identification and mutational analysis of the immunodominant IgE binding epitopes of the major peanut allergen Ara h 2," *Arch. Biochem. Biophys.* 342, 244-253 (1997).

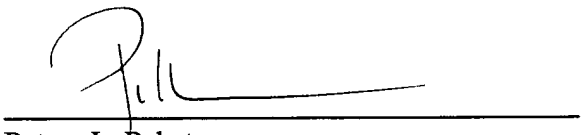
TWARDOSZ, "Molecular Characterization, Expression in Escherichia coli, and Epitope Analysis of a Two EF-Hand Calcium-Binding Birch Pollen Allergen, Bet v 4," *Biochem. Biophys. Res. Commun.* 239: 197-204 (1997).

VRTALA, "High Level Expression in Escherichia coli and Purification of Recombinant Plant Profilins: Comparison of IgE Binding Capacity and Allergenic Activity," *Biochem. Biophys. Res. Comm.* 226: 42-50 (1996).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: January 6, 2000

ARNALL GOLDEN & GREGORY, LLP
2800 One Atlantic Center
1201 W. Peachtree Street
Atlanta, Georgia 30309-3450
(404) 873-8794
(404) 873-8795 (fax)

Certificate of Mailing under 37 C.F.R. § 1.10

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on this date, January 6, 2000, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Mailing Label No. EL320554231US addressed to BOX PATENT APPLICATION, Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: January 6, 2000

Chandra Russell